

# EXHIBIT 16

8475755



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**FILING DATE: *September 12, 2016***  
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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* DECLAN WALSH, DEREK FENLON,  
SIMON KAAR, JAN GEERT HAZENBERG,  
DANIEL BUCK, PAUL CLANCY,  
ROBERT CHARLES USCHOLD, and JEFFREY A. KARG

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Appeal 2019–000453  
Application 15/262,818  
Technology Center 2800

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Before JEFFREY T. SMITH, BRIAN D. RANGE, and  
MERRELL C. CASHION, JR., *Administrative Patent Judges*.

RANGE, *Administrative Patent Judge*.

DECISION ON APPEAL

SUMMARY

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>1</sup> appeals from the Examiner’s decision to reject claims 1–13, 16, 17, and 20–29. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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<sup>1</sup> We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as “TEVA PHARMACEUTICALS, INC., which is the parent corporation of the assignees of record, NORTON (WATERFORD) LIMITED, IVAX PHARMACEUTICALS IRELAND, and TEVA PHARMACEUTICALS IRELAND.” Appeal Br. 2.

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## STATEMENT OF THE CASE<sup>2</sup>

Appellant describes the invention as relating to a metered dose inhaler. Spec. 1:19–22. In particular, the invention seeks to count how many doses of any inhaler have been used while not counting doses where the inhaler canister does not fire. *Id.* at 3:9–28. Claim 1 is illustrative of the claimed subject matter:

1. A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

Appeal Br. 10 (Claims App.).

## REJECTIONS

On appeal, the Examiner maintains the rejection of claims 1–13, 16, 17, and 20–29 under 35 U.S.C. § 103 as unpatentable over O’Leary, US 2002/0078950 A1, Jun. 27, 2002.<sup>3</sup> Ans. 3.

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<sup>2</sup> In this Decision, we refer to the Final Office Action dated July 19, 2017 (“Final Act.”), the Appeal Brief filed May 21, 2018 (“Appeal Br.”), the Examiner’s Answer dated August 7, 2018 (“Ans.”), and the Reply Brief filed October 4, 2018 (“Reply Br.”).

<sup>3</sup> Claims 14, 15, 18, and 19 have been objected by the Examiner as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Final Act. 9. Accordingly, these claims are not before us for review on appeal.

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### ANALYSIS

The Examiner has the initial burden of establishing a *prima facie* case of obviousness based on an inherent or explicit disclosure of the claimed subject matter under 35 U.S.C. § 103. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.”). To establish a *prima facie* case of obviousness, the Examiner must show that each and every limitation of the claim is described or suggested by the prior art or would have been obvious based on the knowledge of those of ordinary skill in the art or the inferences and creative steps a person of ordinary skill in the art would have employed. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

To resolve this appeal, we focus on the Appellant’s arguments that identify error and on the Examiner’s determinations that relate to the error. In particular, the Examiner finds that O’Leary teaches a regulator “that is almost identical to the regulator of the claims.” Ans. 3. The Examiner states “[r]egarding a regulator that acts on the counter in an incremental way, the claim limitations *could* be met *if* there were some kind of complementary features inside of the bobbin 132 that match the nubs 146 of shaft 142.” *Id.* (emphases added). The Examiner determines that it is reasonable to infer such a system from O’Leary based on Figure 15 of O’Leary (reproduced below) and O’Leary’s description of Figure 15. *Id.*



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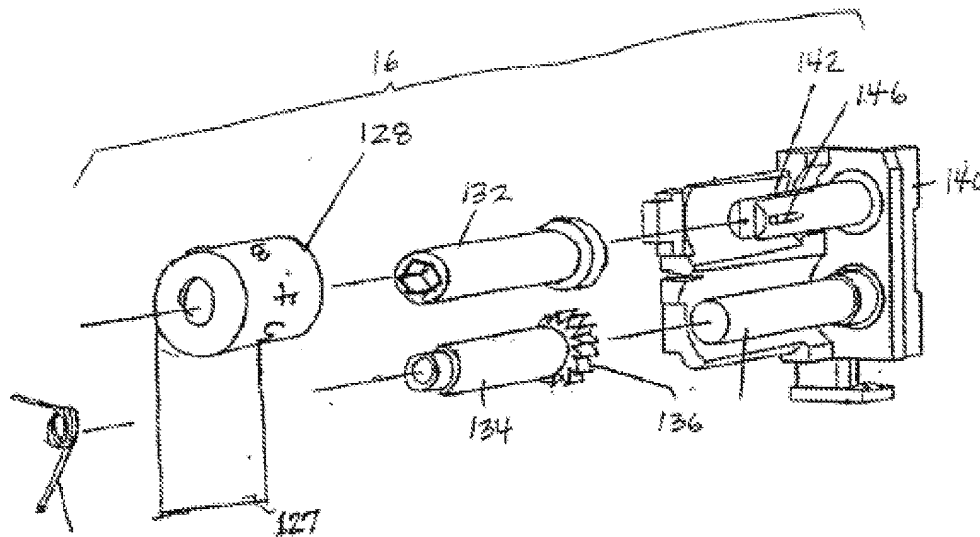


FIG. 15

Figure 15 of O’Leary is an exploded enlarged isometric view of a dose counter. O’Leary ¶ 28. O’Leary describes the pertinent portion of Figure 15 as follows: “The bobbin shaft 142 is preferably forked and includes radially nubs 146 for creating a resilient resistance to rotation of the bobbin 132 on the shaft 142.” *Id.* ¶ 57.

Appellant argues that O’Leary does not suggest a regulator that regulates motion of the counter display of incremental movements as claimed and that the Examiner’s rejection is based on impermissible hindsight. Appeal Br. 5. Appellant’s argument is persuasive. Claim 1 requires a regulator capable of “regulat[ing] motion of the counter display at the first station to incremental movements.” Appeal Br. 10. The Specification explains that incremental movement means rotating from one incremental position to another with, for example, a clicking action. Spec. 5:1–4, 33:19–34:2; *see also* Appeal Br. 3–5.

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The evidence of record does not adequately support the Examiner’s determination that O’Leary’s device is capable of such regulated motion. In particular, O’Leary is ambiguous whether or not bobbin 132 necessarily has complementary features to match the nubs of shaft 142. As Appellant explains, O’Leary merely teaches that its nubs serve to “creat[e] a resilient resistance to rotation of the bobbin 132 on the shaft 142” (O’Leary ¶ 57) and the nubs could serve this purpose without the bobbin having complementary features. Appeal Br. 6–7. While O’Leary’s Figure 15 depicts a hexagonal opening to bobbin 132, it is unclear whether this hexagonal structure continues into the interior of bobbin 132 or engages with the nubs 146. The Examiner has previously conceded as much. Reply Br. 3 (quoting a prior Office Action where the Examiner concedes that “one cannot know for sure that the nubs 146 in figure 15 of O’Leary interact with the hexagonal opening of bobbin 132”). Appellant persuasively explains that O’Leary may have included nubs for other reasons. Reply Br. 4–5

Furthermore, even if the evidence adequately supported that O’Leary nubs 146 interact with the hexagonal structure or some other corresponding structure of bobbin 132, it is not clear that the interaction would, as the Examiner contends, necessarily result in incremental movement. Ans. 7 (“During rotation, the nubs 146 will alternately slip into the corners of the hexagon (resisting movement) and slide along the sides of the hexagon (promoting movement).”). The Examiner has the burden of adequately supporting the obviousness rejection in the first instance, and here, the Examiner fails to establish that a person of skill in the art would have reached a regulator capable of regulating motion in the manner claim 1 recites based upon the teachings of O’Leary or otherwise.



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For this reason above, we do not sustain the Examiner’s rejection of claim 1. Because the Examiner’s treatment of the dependent claims does not cure the error addressed above, we also do not sustain the rejection of those claims.

### DECISION

In summary:

<b>Claims Rejected</b>	<b>Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
1–13, 16, 17, 20– 29	§ 103 O’Leary		1–13, 16, 17, 20–29
<b>Overall Outcome</b>			1–13, 16, 17, 20–29

REVERSED